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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,891

10/15/2003

Amir J. Tehrani

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EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

09/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/686,891	Applicant(s) TEHRANI, AMIR J.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 123-127, 141, 142 and 149-158 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 123-127, 141, 142 and 149-158 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 123-127, 141-142 and 149-158 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

The Applicant argues that "Scheiner et al. stimulates the patient in the absence of a breath and not while the patient is breathing and teaches stimulation to treat disordered breathing" (on page 10 of the Arguments).

However, Scheiner et al. discloses "monitoring a signal representing a patient's respiratory activity, and delivering an electric stimulus from a lead to the phrenic nerve when the signal indicates that the respiratory activity is below a predetermined level". The delivering of stimulation when the respiration does not meet a threshold does not necessarily mean there is an absence of breath. The patient receives stimulation when there is respiration that is not at a sufficient amount to meet the threshold value and thus manages respiration.

In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR*

International Co. v. Teleflex, Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, examiner does not rely on Meer to teach “that phrenic nerve or diaphragmatic pacing alone is insufficient for treating disordered breathing” (on page 11 of the Arguments).

In fact the examiner relies on Meer to disclose “that it is well known to sense the electrical activity of the phrenic nerve in order to determine respiratory information”. Thus Meer discloses that it is known to determine respiratory information from the phrenic nerve and thus it would be obvious to modify the phrenic nerve stimulation system of Scheiner et al. with the sensing of the phrenic nerve as disclosed by Meer in order to provide the predictable results of providing reliable respiratory information while reducing the number of implanted leads and sensors (i.e., by applying a sensing and stimulating electrode on the phrenic nerve).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 123-127, 141-142 and 149-158 are rejected under 35 U.S.C. 103(a) as obvious over Scheiner et al. (US 6,415,183) in view of Meer (US 4,830,008). Scheiner et al. discloses at least one sensor configured to sense respiratory information and at least one electrode coupled to the tissue in order to stimulate the tissue to elicit a diaphragm response. This stimulation therapy sequence is depicted in figure 4.

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Scheiner et al. also discloses the employment of an IPG in order to respond to the sensed signals and deliver stimulation to the electrodes. Additionally, the electrical stimulation of the diaphragm creates a different inspiration volume than the intrinsic volume. Since Scheiner et al. regulates respiration and disordered breathing, Scheiner et al. necessarily creates an inspiration volume that is different than the disordered intrinsic volume since the regulated inspiration volume provides an improvement over the disorder volume.

Additionally, Scheiner et al. discloses the sensing of the minute ventilation with "is a respiratory related parameter that is a measure of the volume of air inhaled and exhaled during a particular period of time. The minute ventilation is the product of respiration rate and tidal volume" (col. 5, lines 46-49). Thus Scheiner et al. measure an inspiration and exhalation volume of an intrinsic breath. By applying stimulation to treat the patient, Scheiner et al. elicits a diaphragm response to provide respiratory improvement such that the inspiration volume is different (i.e., improved) over the intrinsic inspiration volume.

Scheiner et al. discloses the device substantially as claimed except for the sensing of the phrenic nerve activity. Meer teaches that it is well known to sense the electrical activity of the phrenic nerve in order to determine respiratory information. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the phrenic nerve stimulation system of Scheiner et al. with the sensing of the phrenic nerve as disclosed by Meer in order to provide the predictable results of providing reliable respiratory information while reducing the number of

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implanted leads and sensors (i.e., by applying a sensing and stimulating electrode on the phrenic nerve).

Furthermore, such a modification to the system to include one sensing/stimulating electrode would have been obvious to one having ordinary skill in the art at the time the invention was made since it was known in the art of implantable medical devices to employ sensing/stimulating electrodes in order to reduce the amount of implanted leads and sensors.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762